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## NOTICE OF ALLOWANCE AND FEE(S) DUE

79975      7590      01/04/2011

King & Spalding LLP  
P.O. Box 889  
Belmont, CA 94002-0889

EXAMINER	
GOON, SCARLETT Y	
ART UNIT	PAPER NUMBER
1623	
DATE MAILED: 01/04/2011	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,571	07/13/2007	Glenn D. Prestwich	67934-8006.US00	6987

TITLE OF INVENTION: MODIFIED MACROMOLECULES AND ASSOCIATED METHODS OF SYNTHESIS AND USE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	04/04/2011

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

**HOW TO REPLY TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Stop ISSUE FEE  
 Commissioner for Patents  
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**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

79975            7590            01/04/2011

King & Spalding LLP  
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 Belmont, CA 94002-0889

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### Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,571	07/13/2007	Glenn D. Prestwich	67934-8006.US00	6987

TITLE OF INVENTION: MODIFIED MACROMOLECULES AND ASSOCIATED METHODS OF SYNTHESIS AND USE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	04/04/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
GOON, SCARLETT Y	1623	514-054000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
 2 \_\_\_\_\_  
 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted:

Issue Fee  
 Publication Fee (No small entity discount permitted)  
 Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

A check is enclosed.  
 Payment by credit card. Form PTO-2038 is attached.  
 The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  
 b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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King & Spalding LLP P.O. Box 889 Belmont, CA 94002-0889		GOON, SCARLETT Y		
		ART UNIT		PAPER NUMBER
		1623		
DATE MAILED: 01/04/2011				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 527 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 527 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/581,571	PRESTWICH ET AL.	
	Examiner	<b>Art Unit</b>	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 22 November 2010.
2.  The allowed claim(s) is/are 4,5,7,51,52,200,224-226,229,230,234-237,239,240 and 242-244.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

/SCARLETT GOON/  
Examiner, Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 15 December 2010, a proposed amendment in condition for allowance was discussed with Ms. Susan T. Evans, Applicants' attorney, in a telephone interview. Authorization for this examiner's amendment was given in a telephone interview with Ms. Susan T. Evans on 15 December 2010.

The application has been amended as follows:

- Claims 4, 7 and 224 have been amended, as listed below.
- Claim 2 has been cancelled, as listed below.
- Note: For those claims that are neither amended nor canceled as indicated in this Examiner's Amendment, see the amendment filed on 22 November 2010.

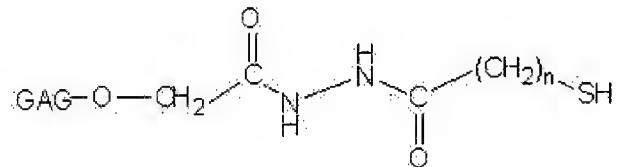
2. (Cancelled)

4. (Currently Amended) The modified-glycosaminoglycan of claim 225, wherein "GAG-O-" represents the ~~residue of~~ substituted hydroxyl group that is a primary C-6

hydroxyl group contained within an N-acetyl-glucosamine residue present in the hyaluronan.

7. (Currently Amended) The modified-glycosaminoglycan of claim 224, wherein “GAG-O-” represents the ~~residue of a~~ substituted hydroxyl group that is a primary C-6 hydroxyl group contained within a non-uronic acid sugar component of a repeating disaccharide of the glycosaminoglycan.

224. (Currently Amended) A modified glycosaminoglycan corresponding to the structure:



wherein

“GAG” is a glycosaminoglycan selected from the group consisting of chondroitin, chondroitin sulfate, dermatan, dermatan sulfate, heparin, heparan sulfate, and hyaluronan, wherein the GAG possessing possesses a plurality of hydroxyl groups,

“GAG-O” represents a ~~residue of a~~ substituted hydroxyl group on the glycosaminoglycan,

n is 2 or 3, and

0.1% to 40% of the glycosaminoglycan’s primary hydroxyl groups are substituted with -CH<sub>2</sub>C(O)NH-NH-C(O)(CH<sub>2</sub>)<sub>n</sub>-SH.

## **DETAILED ACTION**

Applicants' Amendment and Remarks filed on 22 November 2010, in which claims 1, 3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246 were cancelled, and claims 2, 4, 5, 7, 51, 52, 200, 224, 230, 236, 239, 242 and 244 were amended to change the breadth and scope of the claims, is acknowledged.

Claims 4, 5, 7, 51, 52, 200, 224-226, 229, 230, 234-237, 239, 240 and 242-244 are pending in the instant application and are found to be allowable.

## **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance: The instantly claimed compounds and compositions are not seen to be taught or fairly suggested in the prior art, as discussed below.

Applicants' amendment and arguments, filed 22 November 2010, with respect to the rejection of claim 236 made under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been fully considered and are persuasive as the claim has been amended to clearly indicate what is meant by gelatin-DTPH.

Additionally, the structure of gelatin-DTPH is shown in Figure 8 of the instant application, and a journal article publication by Mironov *et al.* (p. 2056, column 2; p.

2057, Figure 2; PTO-892, Ref. U) clearly supports gelatin-DTPH to be the abbreviated form of the full chemical name recited in claim 236.

Applicants' amendment and arguments, filed 22 November 2010, with respect to the rejection of claims 1-10, 24, 25, 51-53, 200, 227, 228, 239, 240 and 242-244 made under 35 USC § 112, first paragraph, as failing to comply with the written description requirement, have been fully considered and are persuasive because the claims have been cancelled and/or the limitation that was deemed to insert new matter into the claims has been deleted from the claims.

Applicants' amendment and arguments, filed 22 November 2010, and the Examiner's amendment above, with respect to the rejection of claims 1, 7-10, 24, 25, 53, 200, 227, 228, 239, 240 and 242-244 made under 35 USC § 103(a) as being unpatentable over PG Pub No. US 2003/0087877 A1 to Calias *et al.*, in view of U.S. Patent No. 5,874,417 to Prestwich *et al.*, have been fully considered and are persuasive. Claims 1, 8-10, 24, 25, 53, 227 and 228 have been cancelled. Claims 7, 200, 239, 240 and 242-244 have been amended to be dependent from allowable claim 224. These rejections have been withdrawn.

In view of the Examiner's amendment above, the instantly claimed modified glycosaminoglycan corresponding to the structure as recited in claim 224, and compositions comprising the modified glycosaminoglycan as recited in claim 224, is non-obvious over the teachings of the prior art. Although the prior art discloses conjugation of hydrazide linkers to glycosaminoglycans such as hyaluronic acid, one of

ordinary skill in the art would have no motivation to further insert a methylene group between the hydrazide linker and the functional group on GAG, particularly since the prior art teaches that the reactive moieties are the carboxylic acid residue present on hyaluronic acid (or other GAG) with the amine moiety present on a dihydrazide structure.

In view of the cancellation of claims 1-3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246, all rejections made with respect to claims 1-3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246 in the previous Office Actions are withdrawn.

The modified glycosaminoglycan corresponding to the structure as recited in instant claim 224, and compositions comprising the modified glycosaminoglycan as recited in claim 224, are disclosed in the instant Specification. For example, support for the claimed modified glycosaminoglycan corresponding to the structure as recited in instant claim 224 can be found on p. 46-47 of the Specification as filed, and the original claims, and support for the claimed compositions can be found on p. 51 of the Specification as filed, and the original claims. Examples for the synthesis of the modified glycosaminoglycan and their use for supporting the growth of cells is further disclosed. Hence, the instantly claimed modified glycosaminoglycan corresponding to the structure as recited in instant claim 224, and compositions comprising the modified

glycososaminoglycan as recited in claim 224, are enabled and have sufficient written description in the Specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/  
Examiner  
Art Unit 1623